## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

## (19) World Intellectual Property Organization International Bureau





(43) International Publication Date 14 October 2004 (14.10.2004)

**PCT** 

## (10) International Publication Number WO 2004/087190 A1

(51) International Patent Classification7:

A61K 38/00

(21) International Application Number:

PCT/US2004/009485

(22) International Filing Date: 29 March 2004 (29.03.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 60/459,683

2 April 2003 (02.04.2003) US

- (71) Applicant (for all designated States except US): GENIX THERAPEUTICS INC. [US/US]; 505 N. Wolf Road, Wheeling, IL 60090 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): EL-RASHIDY, Ragab [US/US]; 130 Exmoor Court, Deerfield, IL 60015 (US).
- (74) Agents: CEPURITIS, Talivaldis et al.; Olson & Hierl, LTD., 20 North Wacker Drive, 36th Floor, Chicago, IL 60606 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

## Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD FOR THE TREATMENT OF PROSTATE CANCER

(57) Abstract: A method for the treatment of advanced prostate cancer comprises administering to a patient suffering from advanced prostate cancer an androgen suppressing amount of a luteinizing hormone releasing hormone agonist analog and an amount of calcitriol sufficient to enhance the effectiveness of the luteinizing hormone releasing hormone agonist analog against the cancer relative to treatment with the luteinizing hormone releasing hormone agonist analog alone. Preferably the calcitriol is in the form of a stabilized, injectable solution of calcitriol in isotonic saline containing about 1 to about 30 milligrams per milliliter of calcitriol and a sufficient quantity of nonionic surfactant to solubilize the calcitriol therein. Preferably the a luteinizing hormone releasing hormone agonist analog is a nonapeptide or decapeptide agonist, such as leuprolide, goserelin or salts thereof. The method of the present invention affords a surprisingly improved efficacy for treatment of advanced prostate cancer such as androgen-independent prostate cancer (AIPC) or hormone refractory prostate cancer (HRPC) in comparison to treatment with a luteinizing hormone releasing hormone agonist analog alone.

